DEC 1 3 2004

K041623

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

REUSABLE STERILECONTAINER FILTER

14 June 2004

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Matthew M. Hull
Regulatory Affairs Manager
800-258-1946 (phone) x5072
610-791-6882 (fax)

TRADE NAME: Aesculap Reusable Sterilecontainer Filter

COMMON NAME: Reusable Filter

DEVICE CLASS: Class II

PRODUCT CODE: FRG

CLASSIFICATION: 880.6850 - Sterilization Wrap

REVIEW PANEL: General Hospital and Personal Use Devices

INTENDED USE

Aesculap's Reusable Sterile Container Filter is a PTFE (Polytetrafluoroethylene) filter that allows for thorough penetration and evacuation of the sterilant (steam), while maintaining an effective barrier against microbial contamination for a maximum of 2,200 uses. This filter is for use with the Aesculap SterilContainer in prevacuum steam sterilization.

DEVICE DESCRIPTION

Aesculap's Reusable Sterile Container Filters allows for thorough penetration and evacuation of sterilants, while maintaining an effective barrier against microbial contamination. The filters are circular in shape and can be used for up to 2,200 washing and sterilization cycles. Aesculap's Reusable filters are to be used in conjunction with Aesculap's Sterilcontainer System (K792558).

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the Reusable Sterilcontainer Filter (when used in the Aesculap Sterilcontainer System) is substantially equivalent in its intended use, function, and basic operating principles to the following predicate devices:

- Aesulap's Sterilcontainer System (K792558)
- Johnson & Johnson's Sterion container (K850289)
- Medline's Steriset container (K010825)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

Mr. Matthew M. Hull
Regulatory Affairs Manager
Aesculap, Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K041623
Trade/Device Name: Reusable Sterilcontainer Filter
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 12, 2004
Received: November 15, 2004

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041623

Device Name: Reusable Sterilcontainer Filter

Indications for Use:

Aesculap's Reusable Sterilcontainer Filter (JK090) is a PTFE (Polytetrafluoroethylene) filter that allows for thorough penetration and evacuation of the sterilant (steam), while maintaining an effective barrier against microbial contamination for a maximum of 2,200 uses. This filter is for use with the Aesculap Sterilcontainer System in prevacuum steam sterilization cycle for 5 minutes at 273° F.

Prescription Use _____ or Over-the-Counter Use X

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Signature MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041623

(Optional Format 3-10-98)